

1 **Saul Perloff (157092)**
2 saul.perloff@shearman.com
3 **Katharyn Grant (pro hac vice)**
4 kathy.grant@shearman.com
5 **Andre Hanson (pro hac vice)**
6 andre.hanson@shearman.com
7 **Olin "Trey" Hebert (pro hac vice)**
8 trey.hebert@shearman.com
9 **SHEARMAN & STERLING LLP**
10 300 W. Sixth Street, 22nd Floor
11 Austin, Texas 78701
12 Telephone (512) 647-1900

13 **Lillian Mao (267410)**
14 lillian.mao@shearman.com
15 **SHEARMAN & STERLING LLP**
16 1460 El Camino Real, 2nd Floor
17 Menlo Park, CA 94025
18 Telephone (650) 838-3600

19 **Christopher LaVigne (pro hac vice)**
20 christopher.lavigne@sherman.com
21 **SHEARMAN & STERLING LLP**
22 599 Lexington Ave
23 New York, NY 10022
24 Telephone (212) 848-4000

25 **Attorneys for Plaintiff**
26 **GUARDANT HEALTH, INC.**

27 UNITED STATES DISTRICT COURT
28 NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

29 GUARDANT HEALTH, INC.,
30 a Delaware corporation,

31 Plaintiff,

32 vs.

33 NATERA, INC.,
34 a Delaware corporation,

35 Defendant.

Case No. 3:21-cv-04062-EMC

[SEALED]

**PLAINTIFF GUARDANT HEALTH, INC.'S
MOTION TO EXCLUDE TESTIMONY
OFFERED BY NATERA'S PUTATIVE
EXPERT JEFFERY A. STEC, PH.D.**

Date: December 15, 2022
Time: 1:30 pm
Place: Courtroom 5

1 **TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD HEREIN:**

2 **PLEASE TAKE NOTICE** that on December 15, 2022, at 1:30 p.m., or as soon thereafter
3 as this matter may be heard in Courtroom 5 of the United States District Court for the Northern
4 District of California, San Francisco Division, located in the United States Courthouse at 450
5 Golden Gate Avenue, San Francisco, California, 94102, the Honorable Edward M. Chen presiding,
6 Plaintiff/Counter Defendant Guardant Health, Inc. (“Guardant”), by and through its attorneys, will
7 hereby respectfully move the Court for an Order excluding testimony offered by Natera, Inc.’s
8 putative expert Jeffery A. Stec, Ph.D..

9 This motion is made upon this notice, the attached memorandum of points and authorities,
10 the declaration of Saul Perloff and exhibits thereto, all records, papers, and pleadings on file in this
11 action, and all further evidence as may be presented prior to or after the filing of the motion.

12 Dated: October 14, 2022

SHEARMAN & STERLING, LLP

13 By: /s/Saul Perloff
14 Saul Perloff

15 Attorney for Plaintiff
16 GUARDANT HEALTH, INC.
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MEMORANDUM OF POINTS AND AUTHORITIES

Plaintiff Guardant Health, Inc. (“Guardant”) respectfully moves to exclude unreliable and improper expert opinion, testimony and argument by Jeffery A. Stec, Ph.D., in support of Defendant/Counter-Plaintiff Natera, Inc., as expressed in his Opening Expert Report (Aug. 22, 2022) (“Stec Report”) (Ex. 1339), his Rebuttal Expert Report (Sep. 13, 2022) (“Stec Rebuttal”) (Ex. 1340), and his Supplemental Export Report (Sept. 19, 2022) (“Stec Supp.”) (Ex. 1341).

I. INTRODUCTION

In this false advertising case, Natera retained Dr. Jeffery A. Stec, an economist and Managing Director at Berkely Research Group, to provide testimony related to Natera’s damages claims and to rebut any damages analysis presented by Guardant. Dr. Stec opined on the disgorgement of Guardant’s revenues, the “corrective” advertising costs Natera incurred in attacking Guardant and Reveal, and the advertising costs Natera claims that Guardant expended in making its alleged “false and misleading” statements. Though Dr. Stec devotes 25 pages of his opening expert report to these issues and over 50 pages of Exhibits, his opinion amounts to [REDACTED] Ex. 1342 (“Stec Dep.”) at 216:20-23. Dr. Stec serves as a human calculator, [REDACTED]. Dr. Stec conducted no expert analysis on whether these amounts are, in fact, attributable to Guardant’s alleged false and misleading advertising, which is a necessary predicate for recovery under the Lanham Act. [REDACTED]

[REDACTED] This is not expert testimony and will not assist the jury in resolving disputed issues of fact. It simply is a means for Natera to introduce its narrative through the guise of expert testimony. It should be excluded.

Dr. Stec also submitted a rebuttal report to the damages expert of Guardant, James Malackowski, who computed the disgorgement amount of Natera’s revenues. Unlike Dr. Stec, [REDACTED]

[REDACTED] In response, Dr. Stec prepared a so-called multi-variate

1 regression analysis [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]

5 This regression analysis, however, is unreliable for several independent reasons. *See*
 6 Declaration of James Malackowski (Ex. 1347) (“Malackowski Decl.”) at ¶ 11. [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 [REDACTED]
 10 [REDACTED]
 11 [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED]

18 [REDACTED] This testimony fails to pass muster under *Daubert v. Merrell Dow Pharms., Inc.*, 509
 19 U.S. 579, 589-92 (1993), and will not assist the trier of fact in resolving disputed issues. Dr. Stec’s
 20 testimony should be excluded.

21 II. STATEMENT OF THE ISSUES TO BE DECIDED

22 Should Dr. Stec be precluded from offering unsupported and irrelevant opinions:

- 23 • Concerning the proper disgorgement amount, Guardant advertising costs, and
 24 Natera corrective advertising costs, when Dr. Stec’s analysis consisted of basic
 25 mathematical calculations based on overbroad assumptions and [REDACTED]; and
- 26 • Concerning his regression model or any conclusions therefrom based on the
 27 model’s flawed methodology, inherent unreliability, and limited conclusions that
 28 Dr. Stec can draw from it;

III. STANDARD OF REVIEW

Under Rule 702, a witness qualified as an expert in “scientific” knowledge may testify thereto, if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702; *San Francisco Baykeeper v. W. Bay Sanitary Dist.*, 791 F. Supp. 2d 719, 736 (N.D. Cal. 2011) (Chen, J.).

Expert testimony is admissible only if it is reliable, relevant, and will assist the jury in determining the facts at issue or understanding the subject matter at hand. FED. R. EVID. 702; *Daubert*, 509 U.S. at 589-92; *see also United States v. Hanna*, 293 F.3d 1080, 1086 (9th Cir. 2002) (admissible expert testimony must address “an issue beyond the common knowledge of the average layperson” (quoting *United States v. Morales*, 108 F.3d 1031, 1039 (9th Cir. 1997))).

District courts act as gatekeepers to ensure that expert testimony admitted into evidence is both reliable and relevant. *San Francisco Baykeeper Corp.*, 791 F. Supp.2d at 736. This two-step assessment requires consideration of whether:

- (1) the reasoning or methodology underlying the testimony is scientifically valid (the reliability prong); and
- (2) whether the reasoning or methodology properly can be applied to the facts in issue (the relevancy prong).

Daubert, 509 U.S. at 592-93; *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1228 (9th Cir. 1998). To be “reliable,” testimony must be grounded in the methods and procedures of science and signify something beyond “subjective belief or unsupported speculation.” *Stonebrae v. Toll Bros.*, 2011 WL 1334444 (N.D. Cal. Apr. 7, 2011) (quoting *Daubert*, 509 U.S. at 590).

The party who presents an expert bears the burden of proving each element necessary to the admissibility of that expert’s testimony and report. *Lust By and Through Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). “It is for the District Court, in the first instance, to determine whether [] statistics appear sufficiently probative of the ultimate fact in issue

1” *Dothard v. Rawlinson*, 433 U.S. 321, 338 (1977) (Rehnquist, J., Concurring); *see also*
 2 *Grasshopper House, LLC v. Clean and Sober Media, LLC*, No. 19-56008, 2021 WL 3702243, at
 3 *1 (9th Cir. Aug. 20, 2021) (“District courts are also ‘entitled to broad discretion when discharging
 4 their gatekeeping function’ under *Daubert*”) (affirming exclusion of damages expert because “Dr.
 5 Williams had not applied a reliable methodology in assessing causation of damages because he
 6 discounted competing causal factors without an adequate basis and lacked the necessary expertise
 7 to make those judgments.”) (quoting *United States v. Alatorre*, 222 F.3d 1098, 1101 (9th Cir.
 8 2000)).

9 IV. ARGUMENT

10 A. Dr. Stec’s Opinions On Disgorgement, Corrective Advertising, and Guardant’s 11 Advertising Costs Should Be Excluded Under Rules 702 and 403

12 In his expert opinion, Dr. Stec concludes that [REDACTED]
 13 [REDACTED]
 14 [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 [REDACTED]

19 [REDACTED] Such testimony is inadmissible as it would not
 20 assist the jury in resolving disputed issues and would cause Guardant unfair prejudice by
 21 introducing purely factual propositions through the imprimatur of expert testimony. The testimony
 22 should be excluded.

23 Expert testimony must assist the jury in understanding the evidence or determining a fact
 24 in issue. FED. R. EVID. 702. “Expert testimony assists the trier of fact when it provides information
 25 beyond the common knowledge of the trier of fact.” *U.S. v. Finley*, 301 F.3d 1000, 1008 (9th Cir.
 26 2002). Opinions should be excluded “[i]f expert testimony merely goes to matters which the finder
 27 of fact ‘is capable of understanding and deciding without the expert’s help.’” *ReBath LLC v. HD*
 28 *Solutions LLC*, No. 19-cv-04873, 2022 WL 2527113, at * 5 (D. Ariz. July 7, 2022) (quoting *U.S.*

1 *v. Castillo*, 924 F.2d 1227, 1232 (2d. Cir. 1991); *Aya Healthcare Servs., Inc. v. AMN Healthcare,*
 2 *Inc.*, No. 17-cv-205, 2020 WL 2553181, at *6 (S.D. Cal. May 20, 2020) (“Expert testimony is
 3 inadmissible if it addresses lay matters which a jury is capable of understanding and deciding
 4 without the expert’s help.”) (internal citation and quotation omitted); *see also Mesfun v. Hagos,*
 5 No. 03-cv-02182, 2005 WL 5956612, at * 2 (C.D. Cal., Feb. 16, 2005) (“[B]ecause expert
 6 testimony carries special dangers for the fact-finding process, courts must exclude it under Rules
 7 702 and 403 ‘unless they are convinced that it speaks clearly and directly to an issue in dispute in
 8 the case, and that it will not mislead the jury.’”) (quoting *Daubert v. Merrell Dow Pharms. Inc.*, 43
 9 F.3d 1311, 1321 n.17 (9th Cir. 1995)).

10 Moreover, the law does not permit experts to “lend their credentials and reputations to the
 11 party who calls them without bringing much if any relevant knowledge to bear on the facts actually
 12 at issue.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp.2d 531, 538 (S.D.N.Y. 2004); *see also In*
 13 *re. Pac. Steel Casting Co.*, No. 19-40193, 2022 WL 3330422, at * 7-8 (Bankr. N.D. Cal. Apr. 10,
 14 2022) (excluding expert testimony concerning “inappropriate factual narratives,” including
 15 “factual characterizations in the ‘Timeline of Significant Events,’ and analyses of deposition
 16 testimony); *Biotech. Value Fund, L.P. v. Celera Corp.*, No. 13-032 48, 2015 WL 138168, at *2
 17 (N.D. Cal. Jan. 9, 2015) (“[W]here the expert does little more than read depositions and deposition
 18 exhibits and other such materials, and then proposes to render findings . . . as to what happened,
 19 [the court] should draw the line and bar such testimony”).

20 **1. Dr. Stec’s Testimony Concerning Guardant’s Disgorgement Will Not Assist The**
 21 **Trier of Fact**

22 Dr. Stec asserts [REDACTED]
 23 [REDACTED]
 24 [REDACTED]
 25 [REDACTED]
 26 [REDACTED]
 27 [REDACTED]
 28 [REDACTED]

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[REDACTED]

[REDACTED] This is notwithstanding the fact that disgorgement damages are appropriate only to the extent “profits *from the infringing activity*” have been established “*with reasonable certainty.*” *Grasshopper House*, 2021 WL 3702243, at *2 (emphasis added); *Farley Transp. Co., Inc. v. Santa Fe Trail Transp. Co.*, 786 F.2d 1342, 1352 (9th Cir. 1985) (remanding for a new trial on damages because the expert witness “provided *no* evidence on the *amount* of damages attributable only to unlawful conduct”).¹

Satisfied at being a human calculator, [REDACTED]

[REDACTED]

¹ [REDACTED]

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Courts routinely exclude such proffered expert testimony. *Triad Cap. Mgt., LLC v. Private Equity Cap. Corp.*, No. 07-cv-3641, 2010 WL 10076450, at *3 (Nov. 22, 2010) (excluding testimony because the expert “does nothing more than add up eight line-items of expenses Triad incurred in negotiating and preparing to consummate the deal”); *Master-Halco, Inc. v. Scillia, Dowling & Ntarelli, LLC*, No. 3:09cv1546 (MRK), 2010 WL 2978289, at *3 (D. Conn. Apr. 9, 2010) (“There is absolutely no reason why the jury cannot do [simple math] for itself; in fact juries do these types of calculations all the time.”).

[REDACTED]

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[REDACTED]

[REDACTED] None of this will be helpful to the jury, and it should be excluded on the same grounds that Dr. Stec’s opinion has been excluded in the past. *See Allergan USA, Inc. v Imprimis Pharmaceuticals, Inc.*, No. 8:17-cv-1551 (C.D. Cal.), Dkt. No. 222 at 2 (May 16, 2019) (“Because Stec fails to attribute damages to any or even all of Imprimis’s false ads, or to account a handful of potential alternative factors, Allergan cannot meet its burden to show that Rule 702 and *Daubert* tests have been satisfied.”) (Ex. 1344).

2. Dr. Stec’s Testimony on Natera’s Corrective Advertising Costs Will Not Assist the Trier of Fact.

Dr. Stec’s testimony on corrective advertising is infirm for similar reasons [REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

Parroting Natera’s litigation exercise, [REDACTED]

[REDACTED]

[REDACTED]

To recover corrective advertising costs, the corrective advertising “must be reasonable and causally related to the false advertising.” *Mobius Mgmt. Sys., Inc. v. Fourth Dimension Software, Inc.*, 880 F. Supp. 10005, 1025 n. 13 (S.D.N.Y.1994). [REDACTED]

[REDACTED]

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[REDACTED]

Like his disgorgement analysis, Dr. Stec’s “expert” role regarding corrective advertising was to be a human calculator. [REDACTED]

[REDACTED]

There is no basis to allow Dr. Stec to testify as an expert as to these calculations. [REDACTED]

[REDACTED]

[REDACTED] Like the excluded expert in *Master-Halco, Inc. v. Scillia, Dowling & Natarelli, LLC*, Dr Stec’s “task was a narrow one: add up the numbers [Natera’s] counsel told him to add up, apply the interest rate that [Natera’s] counsel told him to apply, and ignore virtually everything else.” No. 3:09-cv-1546, 2010 WL 2978289, at *5 (Apr. 9, 2010); *see*

1 *also ReBath*, 2022 WL 2527113, at * 5 (excluding proffered testimony because the expert’s “final
 2 disgorgement figure is merely ReBath’s royalty percentage rate multiplied by the total lost revenue
 3 figure he calculated,” which is “simple math”) (citing cases); *Triad Cap.*, 2010 WL 10076450, at
 4 *3 (“A jury can do simple math and read . . . [the expert’s] opinion on these points does not assist
 5 the trier of fact to understand the evidence or determine a fact in issue as required by Rule 702.”)
 6 (quotations omitted).

7 In short, allowing Dr. Stec’s testimony regarding corrective advertising would allow him
 8 to “simply parrot or recite the opinions and knowledge of” Natera executives concerning their so-
 9 called corrective advertising expenses. *Ash Grove Cement Co. v. Emps. Ins. of Wausau*, 246 F.R.D.
 10 656, 661 (D. Kan 2007). That will not assist the trier of fact, and will prejudice Guardant by
 11 introducing disputed factual points through the imprimatur of expert testimony. *Dura Auto. Sys.*
 12 *of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 612-14 (7th Cir. 2002) (expert not allowed to be
 13 “mouthpiece” of another person); *City of Tuscaloosa v. Harcros Chems. Inc.*, 158 F.3d 548, 565
 14 (11th Cir. 1998) (statistician’s characterizations of documentary evidence would not assist trier of
 15 fact because “the trier of fact is entirely capable of determining whether or not to draw such
 16 conclusions without any technical assistance from . . . experts”); *King-Indiana Forge, Inc. v.*
 17 *Millennium Forge, Inc.*, No. 1:07-cv-00341, 2009 WL 3187685, at *2 (S.D. Ind. Sept. 29,
 18 2009) (“When an expert’s proffered opinion merely parrots information provided to him by a
 19 party, that opinion is generally excluded”); *Media Sport & Art s. r.l v. Kinney Shoe Corp.*, No. 95-
 20 cv-3901, 1999 WL 946354, at *3 (S.D.N.Y. Oct. 19, 1999) (where “not based on personal
 21 knowledge, but instead on his review of documents and depositions produced by the parties,”
 22 expert’s testimony “may not take the place of that of the individuals who actually negotiated the
 23 deal.”) Because “[t]here is nothing that [Dr. Stec] was asked to do that a jury of laypeople could
 24 not do equally well,” *AgroFresh Inc. v. Essentiv LLC*, No. 16-cv-662, 2019 WL 9514565, at *2
 25 (D. Del. Oc. 7, 2019) (quotations omitted), his testimony should be excluded.

26 **3. Dr. Stec’s Testimony Regarding Guardant’s Advertising Costs Will Not Assist** 27 **The Trier of Fact**

28 Dr. Stec’s opinion concerning Guardant’s advertising expenses similarly fails. [REDACTED]

1 [REDACTED]
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]

8 The case cited by Dr. Stec in support of using an advertising spend as a proxy for damages,
9 *Craigslist, Inc. v. Mesiab*, No. 08-cv-5064, 2010 WL 5300883 (N.D. Cal. Nov. 15, 2010), is
10 inapposite. The case involved a default judgment, and the amount of damages under the Lanham
11 Act were not in dispute. *Id.* at *9 (“Defendants stipulate to the \$119,744.48 of total actual damages
12 that Craigslist requests”). And “because Defendants have stipulated to the amount Craigslist seeks
13 to recover, the” court declined to “dedicate any further analysis to this issue.” *Id.* at *13. While the
14 court, in *dicta*, cited *U-Haul Int’l, Inc. v. Jartran, Inc.*, 793 F.2d 1034 (9th Cir. 1986), as creating
15 a “presumption” regarding damages, 2010 WL 5300883, at *13, this is incorrect. *U-Haul*
16 recognized that *literally false* advertising creates a presumption of *deception*, 793 F.2d at 1040-
17 41. While the Ninth Circuit affirmed an award of corrective advertising costs that included, as a
18 component, the defendant’s own advertising expenditures, this sounded in disgorgement, and was
19 “not clearly erroneous” in light of the “detailed evidence that the court had of Jartran’s swift
20 revenue growth and the connection of that growth to Jartran’s advertising.” *Id.* at 1042.

21 Dr. Stec cites no such “detailed evidence,” nor any connection between Guardant’s
22 advertising and any “swift revenue growth.” [REDACTED]

23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED]
28 [REDACTED]

1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 [REDACTED]
 5 [REDACTED]

6 Dr. Stec's assessment both misconstrues controlling authority, misstates the record on
 7 Guardant's actual advertising spend, and fails entirely to connect that spend to any unjust
 8 enrichment—much less tie expenditures to false advertising. None of this is helpful to the jury,
 9 and the Court will assess for itself the propriety of allowing Lanham Act damages based on
 10 Guardant's advertising expenses.

11 **4. Dr. Stec's Testimony Regarding Guardant's Disgorgement, Natera's Corrective**
 12 **Advertising, and Guardant's Advertising Costs Should Also Be Excluded Under**
 13 **Rule 403**

14 If expert opinion can satisfy the requirements of Rule 702, it is still subject to exclusion "if
 15 its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the
 16 issue [or] misleading the jury." FED. R. EVID. 403. Rule 403 plays a critical role in the scrutiny of
 17 expert testimony "given the unique weight such evidence may have in a jury's deliberations."
 18 *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005). Because "[e]xpert evidence can be
 19 both powerful and quite misleading, . . . the judge in weighing possible prejudice against probative
 20 force under Rule 403 . . . exercises more control over experts than over lay witnesses." *Daubert*,
 21 509 U.S. at 595 (quoting Hon. Jack B. Weinstein, Rule 702 of the Federal Rules of Evidence Is
 22 Sound; It Should Not Be Amended, 138 F.R.D. 631, 632 (1991)).

23 Dr. Stec's testimony should be excluded under Rule 403. [REDACTED]
 24 [REDACTED]
 25 [REDACTED]

26 [REDACTED] its admission will only serve to confuse the jury and unduly prejudice Guardant. The proper
 27 evidence to assess Natera's damages claims is within the admissible documents and sworn
 28 testimony of lay witnesses, not the recitation of numbers by a human calculator.

B. Dr. Stec's Multivariate Regression Analysis and Opinions Are Unreliable, Misleading, and Inadmissible.

In an attempt to obfuscate Guardant's claim for disgorgement through a series of statistical buzzwords and equations, Dr. Stec prepared a multivariate regression analysis [REDACTED]

[REDACTED] Dr. Stec's regression analysis relies on multiple unreliable steps, and the unreliability of each of these fundamental mistakes renders Dr. Stec's analysis inadmissible. *See Metabyte v. Canal + Techs.*, No. 02-cv-05509, 2005 WL 6032845 (N.D. Cal., June 17, 2005) ("[A]ny step that renders [an expert's] analysis unreliable [under the *Daubert* factors] renders the expert's testimony inadmissible." (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994))).

1. Dr. Stec's Multivariate Analysis

Multiple linear regression, also known as multivariate regression, is a statistical approach that attempts to model the relationship between a dependent variable and multiple independent variables. Malackowski Decl. (Ex. 1347) at ¶ 13. The model is expressed as an equation. This regression equation can be used to show the strength of the current relationship between both groups of variables, as well as forecast the continued relationship between independent and dependent variables. *Id.* [REDACTED]

[REDACTED] Stec Report (Ex. 1339) at 10; Stec Supp. (Ex. 1341) at 3, 5.

Dr. Stec uses the following terms in his analysis:

Dependent variable: the variable on the left side of the equation (referenced below) that

changes in response to adjustments in the variables on the right side of the equation. [REDACTED]

[REDACTED] (Ex. 1347) at ¶ 13.

Independent variable: the variable(s) on the right side of the equation (referenced below) that are intended to explain changes in the dependent variable on the left side. *Id.* [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Malackowski Decl. (Ex. 1347) at ¶ 14.

Coefficients: the “answers” provided by regression software. The regression equation for expected value is formed by the sum of multiplying the coefficient with its associated independent variable. These are substituted into the equation to multiply the independent variables in the regression equation.

P-Value: a measure of confidence associated with each coefficient to indicate whether that coefficient is statistically significant. By convention, p-values less than 0.05 are considered to indicate statistical significance, whereas p-values greater than 0.05 are considered statistically insignificant.

[REDACTED]

[REDACTED] The regression applied to a dataset like this one can be run in statistical analysis software, such as Microsoft Excel, to solve for the best guess coefficients of the following equation:

$$Y_t = \alpha_0 + \beta_1 P_t + \beta_2 \bar{P}_t + \beta_3 Time + \beta_4 Time^2 + B_5 Spline + \varepsilon_t$$

[REDACTED] A typical regression analysis produces several numerical outputs. Malackowski Decl. (Ex. 1347) at ¶ 15. Most significant for purposes of Dr. Stec’s model are the estimated coefficients and their associated p-values, and Dr. Stec provided these values within the body of his report (and only these values) for each regression. Stec Rebuttal (Ex. 1340) at 9, Figure 2; Stec Supp. (Ex. 1341) at 1, Figure 2; 3, Figure 3. The estimated coefficient for each independent variable and its associated p-value indicate the impact of each independent variable and a measure

1 of statistical confidence in that coefficient, respectively. Malackowski Decl. (Ex. 1347) at ¶ 16.
2 When done properly, a model can be created to estimate the dependent variable as independent
3 variables are changed. Malackowski Decl. (Ex. 1347) at ¶ 13.

4 2. [REDACTED]

5 The p-values in Dr. Stec's model provide a level of confidence for each specific coefficient,
6 or more specifically, confidence in whether that coefficient is statistically significant and
7 appropriately part of the model. Malackowski Decl. (Ex. 1347) at ¶ 17. But a model is only as
8 good as the coefficients that define it; conclusions based on a regression that predominantly
9 comprises statistically insignificant coefficients are, by definition, unreliable.

10 Statisticians, and the Ninth Circuit, recognize that a 0.05 p-value represents a general
11 threshold for evaluating statistical analyses. Malackowski Decl. (Ex. 1347) at ¶ 17; Where p-values
12 associated with a coefficient are greater than .05, they are considered statistically insignificant or
13 unreliable. *See Contreras v. City of Los Angeles*, 656 F.2d 1267, 1272-73 (9th Cir. 1981) (rejecting
14 statistical analysis where results "were not statistically significant when tested at a .05 level of
15 significance"); *United States v. Harkonen*, No. 08-cv-00164, 2010 WL 2985257, at *6 (N.D. Cal.
16 July 27, 2010) ("As a general matter, if the p-value is less than 0.05, a study's results are considered
17 statistically significant; if greater, than 0.05, the results are generally considered unreliable and not
18 statistically significant.")

19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 P-values greater than 0.05 indicate that the associated coefficient is not statistically significant at
24 the generally accepted 95% confidence level. Malackowski Decl. (Ex. 1347) at ¶ 17.
25 [REDACTED]
26 [REDACTED]
27 [REDACTED]
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Table of Regression P-Values

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

(**Bold** indicates that a coefficient is statistically significant because the P-value is below 0.05).

[REDACTED] Stec Rebuttal (Ex. 1340) at 9; Stec Supp. (Ex. 1341) at 1, 3; Malackowski Decl. (Ex. 1347) at ¶ 17. [REDACTED]

[REDACTED] (Ex. 1347) at ¶ 42.

3. [REDACTED]

[REDACTED] Where, as here, expert testimony “is connected to existing data only by the *ipse dixit* of the expert,” *GE Co. v. Joiner*, 522 U.S. 136, 146 (1997), it is unreliable and inadmissible.

By design, a regression can only provide information about relationships between the values in the dataset. Malackowski Decl. (Ex. 1347) at ¶ 13. To be of statistical value, there must be a connection between the datapoints and the actual real-world things they are intended to represent. *Id.* at 27. [REDACTED]

² The “Intercept” is another output calculated by regression software that is part of the regression equation. It represents the predicted value of the dependent variable if the independent variables were zero. Malackowski Decl. (Ex. 1347) at ¶ 15.

The image is entirely black and contains no visible content.

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10 Accordingly, any statistical result that may be applicable to the Spline cannot be further
11 extended to Natera's false advertising because there is no link between the two. When such a link
12 is missing, a court should "conclude that there is simply too great an analytical gap between the
13 data and the opinion proffered" to admit the testimony. *Joiner*, 522 U.S. at 146. This flawed
14 methodology renders the results of Dr. Stec's regression analysis unreliable. *Cabrera v. Cordis*
15 *Corp.*, 134 F.3d 1418, 1423 (9th Cir. 1998) ("An opinion based on such unsubstantiated and
16 undocumented information is the antithesis of the scientifically reliable expert opinion admissible
17 under *Daubert* and Rule 702.").

18 [REDACTED]
19 [REDACTED] Where a regression analysis
20 fails to account for significant factors that could have impacted the dependent variable, the
21 regression analysis should be excluded. *See Grasshopper House, LLC. v. Clean & Sober Media*
22 *LLC*, 2019 WL 12074086 at *12 (C.D. Cal. July 1, 2019) (expert who "continued to defend his
23 regression analysis as accurate despite the presence of possible confounding or independent
24 factors" was excluded); *In re Wireless Tel. Servs. Antitrust Litig.*, 385 F. Supp. 2d 403, 427
25 (S.D.N.Y. 2005) ("Where an expert conducts a regression analysis and fails to incorporate major
26 independent variables, such analysis may be excluded as irrelevant."). The same result should
27 follow here. [REDACTED]
28 [REDACTED]

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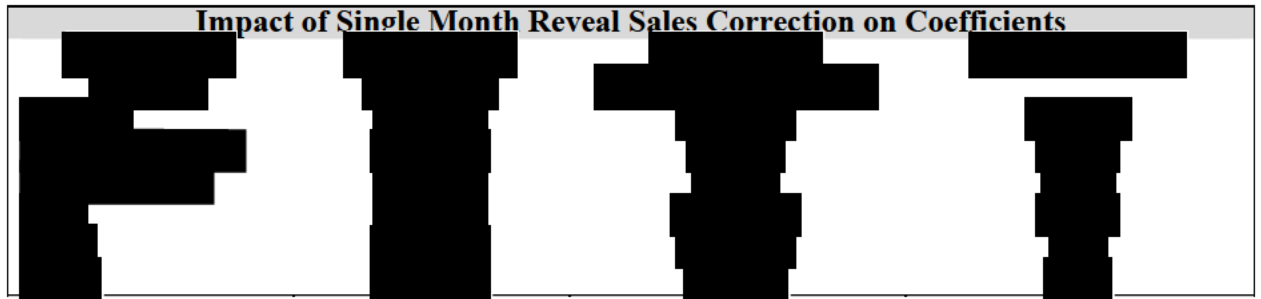
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[REDACTED]

Impact of Removing Time Variable on Coefficients			
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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2 [REDACTED]—his regression model does not withstand Rule 702 analysis and should
3 be excluded. *See Reed Constr. Data Inc. v. McGraw-Hill Cos., Inc.*, 49 F. Supp. 3d 385, 407
4 (S.D.N.Y. 2014) (“But where, as here, very minor changes in arbitrarily selected model parameters
5 can entirely alter the model’s conclusions, that model is insufficiently robust to withstand the
6 scrutiny of Rule 702. Scientific conclusions cannot depend upon the arbitrary choice of
7 parameters.”) *aff’d*, 638 F. Appx. 43 (2d Cir. 2016). [REDACTED]

8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
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21 [REDACTED]
22 Rule 702 requires, among other things, that “the testimony is based on sufficient facts or data.”
23 FED. R. EVID. 702; *See San Francisco Baykeeper.*, 791 F. Supp. 2d at 736. [REDACTED]

24 [REDACTED] A common rule
25 of thumb among statisticians is that there should be a minimum of ten datapoints or observations
26 for every independent variable to be analyzed. Malackowski Decl. (Ex. 1347) at ¶ 46. [REDACTED]
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Multicollinearity is the occurrence of high intercorrelations among two or more independent variables, and it makes estimates derived from regression results “vague, imprecise, and unreliable” and creates an “overfitting problem.” Malackowski Decl. (Ex. 1347) at ¶¶18, 40.

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[REDACTED]

[REDACTED] It completely undercuts the entire purpose of the regression analysis, which was to provide an objective, statistical analysis on the impact of Natera’s false advertising, and makes any conclusions to be drawn from this analysis entirely speculative. *Tsao v. Ferring Pharmaceuticals, Inc.*, 4:16-cv-01724, 2018 WL 3649714 at *15 (S.D. Tex. Apr. 19, 2018) (excluding expert testimony because the opinions were “contrary to . . . her own deposition testimony”); *Beyers v. Consol. Ins. Co.*, No. 119-cv-01601, 2021 WL 1061210, at *11 (S.D. Ind. Mar. 19, 2021) (excluding expert’s opinion as unreliable because his “own testimony contradicts his opinion”). Dr. Stec should not be permitted to have it both ways by tailoring the impact of his regression analysis to whatever best suits Natera in this case.

[REDACTED]

[REDACTED]

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V. CONCLUSION

For the reasons stated above, the Court should bar Natera from offering the unreliable and improper expert opinion and testimony of Jeffery A. Stec, Ph.D., at trial.

Dated: October 14, 2022

SHEARMAN & STERLING, LLP

By: /s/Saul Perloff
Saul Perloff

Attorney for Plaintiff
GUARDANT HEALTH, INC.